Craig Handicap Assessment and Recovery Technique – Short Form (CHART-SF)

Questionnaire Supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials

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Notes to Readers

This supplement is intended to be used with other CDISC User Guides for specific Therapeutic/Disease Areas and follows the CDISC Study Data Tabulation Model Implementation Guide for Human Clinical trials.

Revision History

Date	Version	Summary of Changes
2014-06-25	1.0	Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF) Draft
2014-07-02	1.0	Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF)

1 Introduction

This document describes the CDISC implementation of the Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF) questionnaire. It is a standard questionnaire which was designed to quantify the extent of handicap in individuals by assessing their ability to function in society – their independence, mobility, ability to work and socialize, and financial self-sufficiency.

The CHART-SF questionnaire preceded the CDISC CDASH CRF standards and based on its public domain status, cannot be modified to CDASH standards.

The representation of data collected for this questionnaire is based on the Study Data Tabulation Model Implementation Guide (SDTMIG) QS domain model, which can be found at the CDISC website at: (http://www.cdisc.org/sdtm).

These specific implementation details for this questionnaire are meant to be used in conjunction with the SDTMIG. All questionnaire documentation can be found on the CDISC web site at: (http://www.cdisc.org/content2909).

The CDISC Intellectual Property Policy can be found on the CDISC web site at: (http://www.cdisc.org/bylaws-and-policies).

1.1 Representations and Warranties, Limitations of Liability, and Disclaimers

This document is a supplement to the Study Data Tabulation Model Implementation Guide for Human Clinical Trials and is covered under Appendix F of that document, which describes representations, warranties, limitations of liability, and disclaimers. Please see Appendix F of the SDTMIG for a complete version of this material.

2 Copyright Status

This instrument is in the public domain. CDISC has included the Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF) as part of CDISC Data Standards. Hence, CDISC developed QSTESTCD and QSTEST for each question based on the actual question text on the questionnaire. There may be many versions of this questionnaire. CDISC has chosen to use this version as the data standard.

The CDISC documentation of this instrument consists of: (1) controlled terminology, (2) standard database structure with examples, and (3) case report forms annotated with the CDISC SDTMIG submission values.

Note: CDISC controlled terminology is maintained by NCI EVS. The most recent version should be accessed through the CDISC website. (http://www.cdisc.org/terminology)

The reference for this questionnaire is:
Whiteneck GG, Charlifue SW, Gerhart KA, Overholser JD, Richardson GN. Quantifying handicap: a new measure of long-term rehabilitation outcomes. Arch Phys Med Rehabil. 1992;73:519–526.

3   The QS Domain Model

3.1   Assumptions for Questionnaire Domain Model

All assumptions and business rules described in the SDTMIG QS domain are applicable to this supplement. Additional assumptions specific to the Craig Handicap Assessment and Reporting Technique – Short Form (CHART-SF) questionnaire are listed below.

The questionnaire consists of nineteen items, set apart in five subsections (indicated by QSSCAT level in SDTM) about various handicaps. Some items are fill in the blank; others are multiple choice. The instrument was designed to be administered by interview, either in person or by telephone, taking about 7 to 8 minutes. It is also possible to use the instrument as a mailed or self-administered questionnaire.

1. Some of the CHART-SF multiple choice items are ordinal scale items regarding the severity of a handicap, with a rating (e.g. "I am left alone without anyone checking on me.") and a standardized score (e.g. "6"). The rating text is stored in QSORRES and the standardized number score is stored in QSSTRESN and QSSTRESC.

2. Items 18 and 19 of the CHART-SF contain a rating (e.g. "Less than 15,000") and an instruction along with the response (e.g. "If no code 17,500; if yes ask d"). QSORRES is populated with the rating only for these items. The numbers in the rating instruction are indicated by QSSTREC and QSSTRESN (e.g. "17500"). The complete instruction is considered as a reference for the investigator to use in selecting a rating and thus is not submitted in SDTM. The alphabetical response value (e.g. "a") is also not submitted in SDTM. Please see Section 4 for the complete mapping strategy for these items.

3. There is a scoring worksheet for research analysts to use in determining an overall score for the CHART-SF. This scoring is represented in ADaM, not SDTM. The individual questions are divided into groups to answer five questions which are indicated by QSSCAT levels in SDTM – WHAT ASSISTANCE DO YOU NEED?, ARE YOU UP AND ABOUT REGULARLY?, HOW DO YOU SPEND YOUR TIME?, WITH WHOM DO YOU SPEND TIME?, WHAT FINANCIAL RESOURCES DO YOU HAVE? Analysts will further subcategorize the assistance subcategory into Physical Independence and Cognitive Independence and rescore all items from CHART-SF based on the responses given. They will then determine six subscale scores which can then either be assessed individually or combined to create one overall handicap assessment score. Analysts should refer to the complete Craig Handicap Assessment and Reporting Technique Short Scoring Form and the CHART-SF manual.

4. Terminology:
    a. QSCAT, QSTESTCD and QSTEST are approved CDISC controlled terminology. A full list of value sets for qualifier and result fields is provided in Section 4: SDTM Mapping Strategy.

3.2 Example for Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF) QS Domain Model

The CHART-SF example below shows the terminology used to implement the questionnaire in the QS domain. This example shows the data for one subject collected at VISIT=1 for a CHART-SF questionnaire. The example uses CDISC controlled terminology for QSTESTCD, QSTEST, and QSCAT. All original results are represented with preferred terminology in QSORRES. When applicable, this result is then transformed into a standard numeric score in QSSTRESN and a character representation of the standard numeric score in QSSTRESC.

Rows 1-21: Represent the questions from the CHART-SF form.

qs.xpt

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSORRESU	QSSTRESC	QSSTRESN	QSSTRESU
1	STUDYX	QS	P0001	1	CHSF101A	CHSF1-Paid Personal Care per Day	CHART-SF	WHAT ASSISTANCE DO YOU NEED?	2	HOURS	2	2	HOURS
2	STUDYX	QS	P0001	2	CHSF101B	CHSF1-Unpaid Personal Care per Day	CHART-SF	WHAT ASSISTANCE DO YOU NEED?	2	HOURS	2	2	HOURS
3	STUDYX	QS	P0001	3	CHSF102	CHSF1-Home Cognitive Assistance per Day	CHART-SF	WHAT ASSISTANCE DO YOU NEED?	Sometimes I am left alone for most of the day.		4	4	
4	STUDYX	QS	P0001	4	CHSF103	CHSF1-Away Cognitive Assistance per Day	CHART-SF	WHAT ASSISTANCE DO YOU NEED?	I go to places on my own as long as they are familiar.		3	3	
5	STUDYX	QS	P0001	5	CHSF104	CHSF1-Hours Out of Bed per Day	CHART-SF	ARE YOU UP AND ABOUT REGULARLY?	12	HOURS	12	12	HOURS
6	STUDYX	QS	P0001	6	CHSF105	CHSF1-Days Out of the House per Week	CHART-SF	ARE YOU UP AND ABOUT REGULARLY?	5	DAYS	5	5	DAYS

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSORRESU	QSSTRESC	QSSTRESN	QSSTRESU
7	STUDYX	QS	P0001	7	CHSF106	CHSF1-Nights Away From Home Last Year	CHART-SF	ARE YOU UP AND ABOUT REGULARLY?	1-2		1	1	
8	STUDYX	QS	P0001	8	CHSF107A	CHSF1-Hours of Paid Work per Week	CHART-SF	HOW DO YOU SPEND YOUR TIME?	20	HOURS	20	20	HOURS
9	STUDYX	QS	P0001	9	CHSF107B	CHSF1-Occupation of Paid Work	CHART-SF	HOW DO YOU SPEND YOUR TIME?	Office Assistant		Office Assistant		
10	STUDYX	QS	P0001	10	CHSF108	CHSF1-Hours of Schoolwork per Week	CHART-SF	HOW DO YOU SPEND YOUR TIME?	0	HOURS	0	0	HOURS
11	STUDYX	QS	P0001	11	CHSF109	CHSF1-Hours of Homemaking per Week	CHART-SF	HOW DO YOU SPEND YOUR TIME?	14	HOURS	14	14	HOURS
12	STUDYX	QS	P0001	12	CHSF110	CHSF1-Hours of Home Maintenance per Week	CHART-SF	HOW DO YOU SPEND YOUR TIME?	4	HOURS	4	4	HOURS
13	STUDYX	QS	P0001	13	CHSF111	CHSF1-Hours of Recreation per Week	CHART-SF	HOW DO YOU SPEND YOUR TIME?	0	HOURS	0	0	HOURS
14	STUDYX	QS	P0001	14	CHSF112	CHSF1-Number of People You Live With	CHART-SF	WITH WHOM DO YOU SPEND TIME?	0		0	0	
15	STUDYX	QS	P0001	15	CHSF113	CHSF1-Live With Spouse or Signif Other	CHART-SF	WITH WHOM DO YOU SPEND TIME?	Not Applicable		9	9	
16	STUDYX	QS	P0001	16	CHSF114	CHSF1-Number of Relatives You Live With	CHART-SF	WITH WHOM DO YOU SPEND TIME?	0		0	0	

Row	STUDYID	DOMAIN	USUBJID	QSSEQ	QSTESTCD	QSTEST	QSCAT	QSSCAT	QSORRES	QSORRESU	QSSTRESC	QSSTRESN	QSSTRESU
17	STUDYX	QS	P0001	16	CHSF115	CHSF1-Associates Contacted per Month	CHART-SF	WITH WHOM DO YOU SPEND TIME?	0		0		
18	STUDYX	QS	P0001	19	CHSF116	CHSF1-Friends Contacted per Month	CHART-SF	WITH WHOM DO YOU SPEND TIME?	0		0		
19	STUDYX	QS	P0001	20	CHSF117	CHSF1-Strangers Spoke with Last Month	CHART-SF	WITH WHOM DO YOU SPEND TIME?	0		0		
20	STUDYX	QS	P0001	21	CHSF118	CHSF1-Combined Household Income Last Yr	CHART-SF	WHAT FINANCIAL RESOURCES DO YOU HAVE?	Less than 20,000		17500	17500	
21	STUDYX	QS	P0001	21	CHSF119	CHSF1-Medical Care Expenses Last Year	CHART-SF	WHAT FINANCIAL RESOURCES DO YOU HAVE?	Less than 2,500		1750	1750	

Row	QSBLFL	VISITNUM	QSDTC
1 (cont)	Y	1	2014-06-20
2 (cont)	Y	1	2014-06-20
3 (cont)	Y	1	2014-06-20
4 (cont)	Y	1	2014-06-20
5 (cont)	Y	1	2014-06-20
6 (cont)	Y	1	2014-06-20
7 (cont)	Y	1	2014-06-20
8 (cont)	Y	1	2014-06-20

Row	QSBLFL	VISITNUM	QSDTC
9 (cont)	Y	1	2014-06-20
10 (cont)	Y	1	2014-06-20
11(cont)	Y	1	2014-06-20
12 (cont)	Y	1	2014-06-20
13 (cont)	Y	1	2014-06-20
14 (cont)	Y	1	2014-06-20
15 (cont)	Y	1	2014-06-20
16 (cont)	Y	1	2014-06-20
17 (cont)	Y	1	2014-06-20
18 (cont)	Y	1	2014-06-20
19 (cont)	Y	1	2014-06-20
20 (cont)	Y	1	2014-06-20
21 (cont)	Y	1	2014-06-20

July 2, 2014

4 SDTM Mapping Strategy

Craig Handicap Assessment and Reporting Technique - Short Form (CHART-SF) specific mapping strategy: This section is used for reference with the annotated CRF for further details on the CRF data capture and to understand the alignment of the questionnaire to the SDTM QS domain. It also provides guidance on how the result variables (QSORRES, QSSTRESC, and QSSTRESN) should be populated for the questionnaire.

QSTESTCD=CHSF102 QSTEST= CHSF1-Home Cognitive Assistance per Day

QSORRES	QSSTRESC	QSSTRESN
Someone else is always with me to observe or supervise.	1	1
Someone else is always around, but they only check on me now and then.	2	2
Sometimes I am left alone for an hour or two.	3	3
Sometimes I am left alone for most of the day.	4	4
I have been left alone all day and all night, but someone checks in on me.	5	5
I am left alone without anyone checking on me.	6	6

QSTESTCD=CHSF103 QSTEST= CHSF1-Away Cognitive Assistance per Day

QSORRES	QSSTRESC	QSSTRESN
I am restricted from leaving, even with someone else.	1	1
Someone is always with me to help with remembering, decision making or judgment when I go anywhere.	2	2
I go to places on my own as long as they are familiar.	3	3
I do not need help going anywhere.	4	4

QSTESTCD=CHSF106 QSTEST= CHSF1- Nights Away From Home Last Year

QSORRES	QSSTRESC	QSSTRESN
None	0	0
1-2	1	1
3-4	3	3
5 or more	5	5

QSTESTCD=CHSF113 QSTEST= CHSF1-Live With Spouse or Signif Other

QSORRES	QSSTRESC	QSSTRESN
Yes	1	1
No	0	0
Not applicable (subject lives alone)	9	9

July 2, 2014

QSTESTCD=CHSF117 QSTEST= CHSF1-Strangers Spoke with Last Month

QSORRES	QSSTRESC	QSSTRESN
none	0	0
1-2	1	1
3-5	3	3
6 or more	6	6

QSTESTCD=CHSF118 QSTEST= CHSF1-Combined Household Income Last Yr

QSORRES	QSSTRESC	QSSTRESN
Less than 10,000	5000	5000
Less than 15,000	12500	12500
Less than 20,000	17500	17500
Less than 25,000	22500	22500
Less than 35,000	30000	30000
Less than 50,000	42500	42500
Less than 75,000	62500	62500
75,000 or more	80000	80000

QSTESTCD=CHSF119 QSTEST= CHSF1-Medical Care Expenses Last Year

QSORRES	QSSTRESC	QSSTRESN
Less than 1,000	500	500
Less than 2,500	1750	1750
Less than 5,000	3750	3750
Less than 10,000	7500	7500
10,000 or more	15000	15000

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Page 9
July 2, 2014